

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

**IN RE: TESTOSTERONE REPLACEMENT
THERAPY PRODUCTS LIABILITY
LITIGATION**

**Case No. 1:14-cv-1748
MDL No. 2545
Hon. Matthew F. Kennelly**

THIS DOCUMENT RELATES TO:

All Cases Listed in Exhibit A to Motion

**ACTAVIS, INC.; ACTAVIS PHARMA, INC.;
ACTAVIS LABORATORIES UT, INC.; WATSON LABORATORIES, INC.;
ANDA, INC.; AUXILIUM PHARMACEUTICALS, INC.; PFIZER INC.; AND
PHARMACIA & UPJOHN COMPANY LLC'S
REPLY MEMORANDUM OF LAW IN SUPPORT OF THEIR
MOTION TO DISMISS AND FOR JUDGMENT ON THE PLEADINGS
PURSUANT TO FEDERAL RULES OF CIVIL PROCEDURE 12(b)(6) AND 12(c)**

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I. INTRODUCTION

Plaintiffs’ opposition rests on a single, narrow argument: that where the Food & Drug Administration (“FDA”) designates a medication approved pursuant to an Abbreviated New Drug Application (“ANDA”) as the Reference Listed Drug (“RLD”), the manufacturer of that medication loses the preemption protection it otherwise enjoys under *PLIVA, Inc. v. Mensing*, 564 U.S. ---, 131 S. Ct. 2567 (2011), and *Mutual Pharm. Co. v. Bartlett*, 570 U.S. ---, 133 S. Ct. 2466 (2013). Yet *every federal court* to consider the purported “exception” that Plaintiffs urge, Pls.’ Opp’n at 22 n.8, has squarely rejected it. Two U.S. Courts of Appeals and four U.S. District Courts uniformly have held that because a manufacturer of an ANDA drug that FDA designates as an RLD (an “ANDA RLD”) must obtain FDA approval to change the medication’s label, claims against such manufacturers are preempted under *Mensing* and *Bartlett*. Notably, the latest court to reject Plaintiffs’ proposed RLD “exception” – the U.S. Court of Appeals for the Sixth Circuit, in *In re Darvocet, Darvon, and Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917 (6th Cir. 2014) – did so after considering FDA’s recent guidance on safety labeling.

As if the unanimous opinions of these federal courts and FDA’s guidance were not enough to end the inquiry (which they are), another recent – and even more definitive – FDA statement does. In November 2013, in an analysis of a proposed change to its existing rules, FDA expressly stated that “unless a labeling change already has been requested by FDA,” ANDA holders whose drugs are designated as RLDs “*must contact FDA if they believe that new safety information should be added to their product labeling.*” FDA, Office of Policy & Planning, *Preliminary Regulatory Impact Analysis*, FDA-2013-N-0500 (2013) (“Impact Analysis”), at 9 (emphasis added). (See ANDA Defs.’ Supp. Req. for Judicial Notice (“SRJN”), ¶ 1, Ex. 1.) FDA’s Impact Analysis puts to rest any argument by Plaintiffs that every federal court to interpret FDA’s regulations and guidance has somehow gotten it wrong.

In the face of that wall of judicial and regulatory authority, Plaintiffs rely on the split decision of a single state intermediate appellate court, *In re Reglan / Metoclopramide Litig.*, 74 A.3d 221 (Pa. Super. Ct. 2013). Significantly, though, that court issued its decision *before* FDA issued its safety labeling guidance and Impact Analysis and before the Sixth Circuit rejected the same argument Plaintiffs make here. The *Reglan* Court also expressly limited the import of its opinion by noting that it did “not have the benefit of the FDA’s interpretation of its own regulations,” *id.* at 227, an interpretation that now exists and flatly forecloses Plaintiffs’ position. Thus, Plaintiffs ask this Court not only to break with every federal court to consider the RLD issue, but also to be the first court *anywhere* to tell FDA its interpretation of its regulations is wrong – notwithstanding the U.S. Supreme Court’s instruction that FDA’s view is “controlling” absent plain error. *Mensing*, 131 S. Ct. at 2575. This Court should decline Plaintiffs’ invitation.

So too should the Court decline Plaintiffs’ suggestion that further discovery may be of value because certain remaining ANDA Defendants have used the “Changes Being Effected” (“CBE”) regulation to submit label changes. Additional discovery is neither necessary nor warranted because this motion presents a pure question of law, and (in any event) Plaintiffs have had the remaining ANDA Defendants’ regulatory files for more than seven months.

Given FDA’s clear statements and the unanimity of federal authority rejecting Plaintiffs’ contentions, the ANDA Defendants respectfully request that the Court grant their motion and dismiss Plaintiffs’ claims against them with prejudice.

II. ARGUMENT

A. EVERY FEDERAL COURT TO CONSIDER PREEMPTION IN THE CONTEXT OF AN ANDA RLD HAS HELD THAT *MENSING* PREEMPTION APPLIES.

Plaintiffs devote the opening pages of their opposition to arguing that, under the statutes and regulations that use the term “listed drug,” a manufacturer of an ANDA RLD, unlike other

ANDA manufacturers, can change its label unilaterally using the CBE process. Pls.’ Opp’n at 3-9. On that basis, Plaintiffs assert, warnings-based claims against the manufacturers of an ANDA RLD are not preempted under *Mensing*, and instead fall under the preemption analysis in *Wyeth v. Levine*, 555 U.S. 555 (2009). See Pls.’ Opp’n at 10-12.

It is not until more than halfway through Plaintiffs’ 24-page opposition that they address how other courts considering this purported RLD “exception” have ruled. And with good reason: *Every federal court* to consider the argument Plaintiffs make here – two U.S. Courts of Appeals and four U.S. District Courts – has rejected it. Plaintiffs are left to try to evade that federal authority by arguing that those courts somehow “misapprehended” FDA’s regulations, were “led [] astray” by *Mensing*’s “lack of precision,” or “misunderstood the significance” of FDA’s labeling guidance. *Id.* at 13-15. To the contrary, the preemption of claims involving ANDA RLDs is settled, as federal courts’ unanimous conclusions on the issue demonstrate.

1. *In re Darvocet* Correctly Interpreted FDA’s Safety Labeling Guidance and Was Issued Before FDA’s Even More Definitive Impact Analysis.

Of the federal courts to address the application of *Mensing* to ANDA RLDs, the most recent is the Sixth Circuit in *In re Darvocet*, 756 F.3d 917. There, the plaintiffs argued for the exact same “exception” that Plaintiffs urge here, see Pls.’ Opp’n at 10-12, 22 n.8 – namely, that *Mensing* and *Bartlett* do not supply the applicable preemption analysis because the manufacturer of an ANDA RLD can change its label unilaterally. See 756 F.3d at 933.

The Sixth Circuit unanimously disagreed, and its decision is directly on point. Notably, the *Darvocet* Court was the first to have the benefit of the safety labeling guidance that FDA issued in July 2013. See *id.* (citing FDA, Center for Drug Evaluation and Research, *Guidance for Industry: Safety Labeling Changes—Implementation of Section 505(o)(4) of the FD & C Act* (July 2013) (“Labeling Guidance”), available at <http://1.usa.gov/1cF0bdk>). (See SRJN, ¶ 2, Ex.

2.) In its Labeling Guidance, FDA explained that ANDA holders may use the CBE process to add safety information to their products' labels in only two instances: "[1] to match the RLD labeling or [2] *to respond to FDA's specific request to submit a labeling change under this provision.*" Labeling Guidance at 7 n.10 (emphasis and enumeration added).¹ As FDA also made clear, an ANDA holder may submit a CBE supplement containing safety information where the changes are "identical to those that FDA included in the notification letter" but must seek prior approval if the applicant proposes alternative label language. *Id.* at 7.²

The Sixth Circuit read FDA's Guidance as "confirming that RLD-designation does not alter the obligations of generic manufacturers" and as making "clear" that the rule requiring submission of label changes when new safety information warrants "does not apply to RLD designees whose drug was approved pursuant to an ANDA." 756 F.3d at 933. The court found that FDA's interpretation "makes sense" because its regulations "recognize only two categories of drug applications" – NDAs and ANDAs. *Id.* The court also expressly considered the regulations on which Plaintiffs rely here – those using the term "listed drug" – but concluded that merely having its product designated as an RLD "does not empower a generic manufacturer to independently change the drug's warning label." *Id.* at 934. And, the court added, "[e]very

¹ FDA's Guidance on that point is, not surprisingly, consistent with the CBE regulation itself, which states that an applicant may use the CBE provision to make a change that "FDA specifically requests be submitted under this provision." 21 C.F.R. § 314.70(c)(6)(iii)(E).

² Although not relied on by the *Darvocet* Court, in another part of the Guidance FDA explains that it will notify *each* ANDA holder when it determines that there is safety information that should be added to the label but there is no approved NDA serving as the RLD. In such instances, "[a] holder of an approved NDA . . . or ANDA *without a marketed NDA reference listed drug* (RLD) will be notified and required to make the safety labeling changes . . ." *Id.* at 6 (emphasis added). Where the information applies to more than one applicant, FDA will send the request to "*each* holder of an approved NDA . . . and/or ANDA without a marketed NDA RLD." *Id.* (emphasis added). Thus, where there is no NDA RLD, FDA will notify the ANDA holders – including the ANDA RLD manufacturer – of changes it wants the ANDA holders to make. Had FDA intended to treat ANDA RLDs differently from other ANDAs, there would be no point to adding the qualifier "without a marketed NDA RLD." Rather, FDA could have said that it will notify the NDA holder or the manufacturer of the ANDA RLD – or simply the RLD designee, whether an NDA or ANDA – of the required change. It did not.

federal court to consider this issue has held that FDA’s designation of a generic manufacturer’s drug as the RLD does not subject an ANDA product to NDA, or brand-name, status or requirements.” *Id.*

Plaintiffs claim that the *Darvocet* Court “misunderstood” the language it quoted from the Labeling Guidance and suggest that FDA meant to “qualify its statement” about the inability of ANDA holders to change their labels unilaterally to account for ANDA RLDs. Pls.’ Opp’n at 15. But Plaintiffs’ tortured reading of the Guidance – which requires them to maintain that the language “could have been clearer” and “presumably received less attention” because it was in a footnote, *id.* – is flatly contradicted by FDA’s Impact Analysis issued a few months later.

In November 2013, FDA proposed a change to its current regulations, which would allow ANDA holders to make label changes unilaterally. *See Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products*, 78 Fed. Reg. 67,985, 67,988-89 (Nov. 13, 2013).³ In an analysis of that proposal, FDA noted that it has designated approximately 420 ANDAs as RLDs where the original RLD has been discontinued from the market. *See* FDA’s Impact Analysis at 9. And FDA made clear that manufacturers of those ANDA RLDs *cannot* change the safety information in their labels unilaterally: “Currently, these ANDA holders [those whose products have been designated as RLDs] *must contact FDA if they believe that new safety information should be added to their product labeling* unless a labeling change already has been requested by FDA.” *Id.* (emphasis added). FDA’s Impact Analysis directly refutes Plaintiffs’ argument that an ANDA holder whose product FDA has designated as an RLD “is free to make such changes as it believes are necessary” to its label, Pls.’ Opp’n at 2, and forecloses any claim that the *Darvocet* Court misread FDA’s Labeling Guidance. Because

³ FDA has not finalized the proposed rule and recently held a public hearing to receive additional comments. *See* <http://www.fda.gov/Drugs/NewsEvents/ucm431265.htm>.

FDA's interpretation of its regulations is "controlling" unless it is "plainly erroneous or inconsistent with the regulation[s]," *Mensing*, 131 S. Ct. at 2575, which it is not, this Court should follow *Darvocet* and find that all Plaintiffs' claims are preempted.⁴

2. Other Federal Courts Reached the Same Conclusion as *Darvocet* Even Before FDA Issued Its Guidance and Impact Analysis.

Even before FDA issued its Labeling Guidance and Impact Analysis, and before the Sixth Circuit issued its opinion in *Darvocet*, every federal court to consider FDA's regulations had concluded that manufacturers of ANDA RLDs cannot change their labels unilaterally. For example, in *Moore v. Mylan Inc.*, 840 F. Supp. 2d 1337 (N.D. Ga. 2012), the court rejected the plaintiffs' argument that the manufacturer of an ANDA RLD may use the CBE process to change its product's label, finding nothing in FDA's RLD designation that gave the ANDA holder "the right to use the CBE process to change the label of any of its drugs" *Id.* at 1348. In *Hogue v. Pfizer, Inc.*, No. 2:10-cv-805, 2012 WL 11944897 (S.D. Ohio Sept. 27, 2012), the court likewise observed that "FDA has expressly recognized the RLD designation does nothing to alter an ANDA holder's duties concerning labeling changes." 2012 WL 11944897, at *4. Plaintiffs now criticize both decisions as misstating FDA's interpretation of its own regulations, *see* Pls.' Opp'n at 13, 14, but both courts interpreted the regulations in the same manner as FDA.

Similarly, in *Morris v. Wyeth, Inc.*, No. 09-0854, 2012 WL 601455 (W.D. La. Feb. 23, 2012), the court concluded that even after FDA designates an ANDA drug as the RLD, "FDA retains responsibility for providing guidance to the manufacturers as to any necessary changes to the drug's labeling." 2012 WL 601455, at *6. On that basis, the court rejected plaintiffs' argument that the ANDA holder had a duty to change its label unilaterally. *See id.* While

⁴ Plaintiffs concede all their claims flow from Defendants' alleged failure to warn and the reasoning in their opposition "applies with equal force" to all their claims. Pls.' Opp'n at 17-18. Because failure-to-warn claims involving an ANDA RLD are preempted, Plaintiffs' complaint is preempted in its entirety.

Plaintiffs contend that *Morris* “misapprehended” the applicable legal issue, Pls.’ Opp’n at 14, in fact the *Morris* Court correctly concluded that a manufacturer of an ANDA RLD cannot change its label unilaterally, which is the key point for purposes of impossibility preemption.⁵

In the same way, Plaintiffs attempt to distinguish *Cooper v. Wyeth, Inc.*, No. 09-929-JJB, 2012 WL 733846 (M.D. La. Mar. 6, 2012), on the ground that the plaintiff there did not take the form of the drug made by the manufacturer of the ANDA RLD. See Pls.’ Opp’n at 16 n.6. But again, that was not the issue on which the decision turned. The plaintiffs there cited the very same regulations on which Plaintiffs rely here, but the court found that “plaintiffs’ interpretation of federal law appears at odds with the FDA’s.” 2012 WL 733846, at *8. The court found “no authority authorizing the FDA to elevate the duties of a generic ANDA drug to the level of a brand name NDA drug simply because the FDA chooses that generic as the comparison model for bioequivalency measurements arising from the processing of subsequent ANDAs.” *Id.* at *9.

3. The *Reglan* Decision Is Unpersuasive in Light of FDA’s Definitive Interpretation of Its Regulations.

In the face of unanimous federal-court precedent rejecting their position, Plaintiffs urge this Court to follow the split decision of a lone state intermediate appellate court issued almost a year before the Sixth Circuit unanimously decided the issue in *In re Darvocet*. In July 2013, the same month FDA issued its Labeling Guidance, a Pennsylvania court held that the manufacturer of an ANDA RLD had not met its burden of establishing that *Mensing* preemption applied. See *Reglan*, 74 A.3d at 227; Pls.’ Opp’n at 16-17. In part, that court questioned why FDA would need to designate an ANDA RLD after an original RLD left the market if the ANDA RLD could not use the CBE process. See *Reglan*, 74 A.3d at 227. But the answer to that question is clear:

⁵ Plaintiffs also overlook that the Fifth Circuit affirmed the district court in rejecting Plaintiffs’ argument that a manufacturer of an ANDA RLD can be held liable for an alleged failure to warn. See *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777-78 (5th Cir. 2013).

Future ANDA applicants must have a drug against which to compare their active ingredient, route of administration, dosage form, strength, and bioequivalence, and to match their current labeling, *see* 21 U.S.C. § 355(j)(2)(i)-(v), even if the ANDA RLD cannot use the CBE process.

Tellingly, in issuing its decision, the Pennsylvania court regretted that it did “not have the benefit of the FDA’s interpretation of its own regulations.” *Reglan*, 74 A.3d at 227. That interpretation is now available in FDA’s Labeling Guidance and Impact Analysis, which make clear (as the Sixth Circuit correctly recognized) that manufacturers of ANDA RLDs may not alter their labels unilaterally. As such, *Reglan* is unpersuasive. This Court should not follow it.

B. THE COURT SHOULD NOT ALLOW PLAINTIFFS ADDITIONAL DISCOVERY.

Without any meaningful support in the existing case law or FDA’s interpretations of its regulations, Plaintiffs are left to argue that because a Pfizer predecessor submitted label changes under the CBE regulation, the Court should permit Plaintiffs to take discovery to determine whether the ANDA Defendants made unilateral changes to their labels. *See* Pls.’ Opp’n at 9, 21-22. Plaintiffs’ argument is unpersuasive, for three reasons.

First, an ANDA Defendant’s use of the CBE process is irrelevant to the preemption analysis. As explained above, an ANDA manufacturer may use the CBE process in response to an FDA request. But as the Supreme Court explained in *Mensing*, that does not mean that an ANDA holder may change its label unilaterally. *See Mensing*, 131 S. Ct. at 2575-76. And where a manufacturer cannot change its label unilaterally, but instead has to seek the “approval and assistance” of FDA, impossibility preemption still applies. *Id.* at 2578-79 (noting that the question for impossibility preemption is “whether the private party could independently do under federal law what state law requires of it”); *see id.* at 2581 (finding preemption when a party “cannot satisfy its state duties without the Federal Government’s special permission and assistance”). Thus, an ANDA holder’s use of the CBE process in response to FDA’s instructions

– whether the ANDA holder serves as the RLD or not – is consistent with impossibility preemption and does not provide a sufficient basis to justify further discovery.⁶

Second, no discovery is necessary to resolve the ANDA Defendants’ motion. The preemption analysis requires the Court only to take judicial notice of the fact that FDA approved certain testosterone therapies pursuant to ANDAs rather than NDAs⁷ and then decide the purely legal question of whether the nature of FDA’s approval limits the ANDA Defendants’ ability to change their labels unilaterally. Indeed, Plaintiffs correctly concede that whether the ANDA Defendants could change their labels unilaterally is “primarily a legal question.” Pls.’ Opp’n at 21. For that reason, other courts have rejected requests for discovery in the context of *Mensing* motions. *See* ANDA Defs.’ Mem. of Law, Doc. No. 771, at 22 (citing *Garza v. Wyeth LLC*, No. 2:12-CV-198, 2015 WL 364286, at *4 (S.D. Tex. Jan. 27, 2015); *Wilson v. Amneal Pharms., L.L.C.*, No. 1:13-cv-00333-CWD, 2013 WL 6909930, at *4-*7, *12 (D. Idaho Dec. 31, 2013)).

Third, Plaintiffs have failed to justify additional discovery, which they claim they need to see the ANDA Defendants’ label changes and FDA’s responses. *See* Pls.’ Opp’n at 21. But Plaintiffs already have that information; more than seven months ago, Plaintiffs received the remaining ANDA Defendants’ regulatory files, which consist of thousands of pages of correspondence with FDA and which set forth those ANDA Defendants’ label changes and FDA’s requests and responses related to those changes. Plaintiffs also assert that they may be able to evade preemption by finding evidence that the ANDA Defendants knew or should have known of the need to change their labels prior to the enactment of the Hatch-Waxman Amendments in 1984, *see id.* at 22, but those allegations are found nowhere in the Master

⁶ Even if an ANDA manufacturer did change its label unilaterally, contrary to FDA rules, it would be the responsibility of FDA, not private litigants, to enforce any such violations. *See* 21 U.S.C. § 337(a).

⁷ Plaintiffs do not dispute that the Court can take judicial notice of FDA’s ANDA approvals; in fact, they seek judicial notice of documents establishing just that. *See* Pls.’ Req. for Judicial Notice at 1-2, 4.

Complaint and could not be made consistently with Rule 11. Plaintiffs should not be permitted to prolong this litigation as to the ANDA Defendants by engaging in a fishing expedition, and the Court should reject Plaintiffs' request for discovery.⁸

C. PLAINTIFFS' OFF-LABEL PROMOTION ALLEGATIONS ARE IRRELEVANT TO THE PREEMPTION ANALYSIS.

The ANDA Defendants' opening memorandum showed that Plaintiffs' allegations concerning off-label marketing do not alter the preemption analysis under *Mensing*. See ANDA Defs.' Mem. at 18-19. Plaintiffs do not dispute that proposition or address the cases on which it is based. See Pls.' Opp'n at 18 n.7. Plaintiffs also concede that they "assert no *claim* for fraud on the FDA." *Id.* at 18 (emphasis in original). In light of those admissions and the fact that each of Plaintiffs' claims against the ANDA Defendants is preempted, the Court need not consider the application of *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), to Plaintiffs' claims. See ANDA Defs.' Mem. at 21.⁹

III. CONCLUSION

Plaintiffs cannot overcome clear, controlling FDA guidance and unanimous federal court decisions that manufacturers of ANDA RLDs cannot unilaterally change their labels and therefore are entitled to preemption under *Mensing*. Thus, the ANDA Defendants respectfully request that the Court dismiss Plaintiffs' Master Complaint (and individual complaints) with respect to their ANDA-approved TRTs, with prejudice.

⁸ Plaintiffs also assert that Pfizer distinguished Depo-Testosterone from "generic" drugs in its opposition to their MDL petition. See Pls.' Opp'n at 9-10. But Pfizer merely pointed out that in cases involving plaintiffs who received testosterone cypionate injections, identifying the specific manufacturer presents different discovery and motion issues than in cases involving NDA therapies, where the manufacturer typically is not in question – not that Depo-Testosterone is distinct for purposes of *Mensing* preemption.

⁹ Likewise, because Plaintiffs have agreed to dismiss all claims against the Actavis Defendants relating to their ANDA drugs, see Pls.' Opp'n at 1 n.1, the issues raised by this motion, including the adequacy of the allegations relating to off-label marketing of those Defendants' ANDA products, will become moot once those dismissals are entered. Plaintiffs' allegations involving Androderm are irrelevant, as Defendants' motion does not address claims involving products approved pursuant to an NDA.

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Respectfully submitted,

/s/ Joseph P. Thomas

Joseph P. Thomas

Jeffrey F. Peck

K.C. Green

Jeffrey D. Geoppinger

ULMER & BERNE LLP

600 Vine Street, Suite 2800

Cincinnati, OH 45202

Phone: (513) 698-5000

Fax: (513) 698-5001

E-mail: jthomas@ulmer.com

*Attorneys for Actavis, Inc.; Actavis Pharma, Inc.;
Anda, Inc.; Watson Laboratories, Inc., a Nevada
corporation; and Watson Laboratories, Inc., a
Delaware corporation*

/s/ Andrew K. Solow

Andrew K. Solow

Robert M. Grass

KAYE SCHOLER LLP

250 West 55th Street

New York, NY 10019

Tel: (212) 836-7740

Fax: (212) 836-6776

andrew.solow@kayescholer.com

Pamela J. Yates

KAYE SCHOLER LLP

1999 Avenue of the Stars, Suite 1700

Los Angeles, CA 90067

Tel: (310) 788-1278

Fax: (310) 788-1200

pamela.yates@kayescholer.com

Attorneys for Auxilium Pharmaceuticals, Inc.

/s/ Matthew A. Holian

Loren H. Brown

Cara D. Edwards

DLA PIPER LLP (US)

1251 Avenue of the Americas

New York, NY 10020

Phone: (212) 335-4500

Fax: (212) 335-4501

loren.brown@dlapiper.com

cara.edwards@dlapiper.com

Matthew A. Holian

Jessica C. Wilson

DLA PIPER LLP (US)

33 Arch Street, 26th Floor

Boston, MA 02110

Phone: (617) 406-6000

Fax: (617) 406-6001

Email: matt.holian@dlapiper.com

Email: jessica.wilson@dlapiper.com

*Attorneys for Pfizer Inc. and Pharmacia & Upjohn
Company LLC*

CERTIFICATE OF SERVICE

I, Matthew A. Holian, hereby certify that on June 29, 2015, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notification of such filing to all registered attorneys of record.

/s/ Matthew A. Holian
